GLOBAL LIVESTOCK CRSP

Experience and Challenges in the Recruitment and Retention of HIV-infected Rural Kenyan Women and Their Children into a Randomized Nutrition Intervention Study

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HIV Nutrition Project (HNP)

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Despite the knowledge and information available about HIV, stigma is still present. The affects of stigma are real and tangible. Globally HIV positive people are marginalized and often dread that their HIV status will adversely affect them socially. The belief that HIV-infected people are somehow deviant, or misconceptions about the mode of transmission fuels anxiety, fear, and distrust, which translates into barriers to adequate health care, emotional distress, and actions that can have adverse affects on health outcomes. When working with HIV-infected individuals and those at risk of becoming infected with HIV, the impact of stigma can be crippling to research. Stigma associated with HIV has had a significant role in the ability to recruit and retain eligible study subjects for a nutrition based HIV study, Increasing Animal Source Foods in Diets of HIV-infected Kenyan Women and Their Children (HNP). *While this study specifically focused on HIV-infected women living in Kenya, the generalization gathered could be extrapolated to other populations. It is recommended that similar studies conduct focus groups with the study population prior to piloting, to ensure stakeholder input and an understanding of the particular challenges and concerns within a local context. Future studies should also employ individuals known in the community that the population trusts to assist with recruitment. Finally, factors that identify study staff, or associate subjects with the study should be minimal to reduce the risk of disclosing a subject's HIV status.*

Background

The GL-CRSP supported *Increasing Animal Source Foods in Diets of HIV-infected Kenyan Women and Their Children (HNP)* is a study that evaluates the effect of protein quality and micronutrients found in meat on the health and nutritional well-being of drug naïve women living with HIV in rural Kenya, and the health and development of their children. The study methods include a randomized nutrition feeding intervention. Directly observed treatment (DOT) is used to assure adherence and to quantify food and dietary intake. A DOT field worker delivers the supplement daily to the women and children. Study subjects are randomized to receive either biscuits with added beef, added soy flour, or wheat flour. Hypotheses of the HNP are based on the premise that the protein and micronutrients in beef protect the immune system, prevent severe infection, prevent the loss of lean body mass, and support the growth and development of the children; thus enhancing the quality of life among study subjects.

Patient population. The study population is composed of women that receive medical care at the Turbo Rural Health Center, one of the rural clinics that were established by the United States Agency for International Development Academic Model Providing Access to Healthcare (USAID-AMPATH) Partnership program in Kenya. USAID-AMPATH operates under the joint direction of Moi Teaching and Referral Hospital and the Moi University and Indiana University Schools of Medicine. Since it's inception in late 2001, USAID-AMPATH has enrolled over 100,000 HIV-infected adults and children in 46 care centers in rural and urban areas in western Kenya. Based on the current Kenya Ministry of Health Antiretroviral Treatment Guidelines, only about 50% of USAID-AMPATH patients are eligible for treatment with antiretroviral drugs.

The HNP patient population requires a particularly sensitive approach in research recruitment, enrollment, intervention implementation, outreach, and follow-up due to the social stigmatization of HIV/AIDS in the study area, which is present despite the knowledge and information available about HIV. The affects of stigma are real and tangible. Globally HIV positive people are marginalized and often dread that their HIV status will adversely affect them socially. The belief that HIV-infected people are somehow deviant, or misconceptions about the mode of transmission fuels anxiety, fear, and distrust. This fear translates into barriers to adequate health care, emotional distress, and actions that can have adverse affects on health outcomes. For example, an HIV-infected person may find it difficult to adhere to medical advice if there is a risk that their HIV status will be disclosed. The stigmatization of HIV/AIDS in the HNP study area has had a significant role in the ability to recruit and retain eligible study subjects for our nutrition based HIV study, and has been crippling to HNP research. This research brief discusses the

stigmatization of HIV/AIDS, the challenges for researchers working under stigmatized conditions, and the lessons learned, with the hopes others engaging HIV-infected and affected populations can benefit from the HNP experience in the planning and implementation of future projects and studies.

Preliminary Findings

Recruitment barriers related to stigma. We have observed that disclosure of HIV status deters subjects from enrolling in the study because of stigma. Some women are very comfortable with the disease and have known their HIV status for some time. These subjects are more likely to have a larger support system and are more likely to integrate into AMPATH services. Others recruited shortly after knowing their HIV status may not have developed a support system, and are less likely to be integrated into services. Some study subjects report that they have not even disclosed their HIV status to family members living within their home (i.e. their children). This can make participation in a study like HNP, which targets both mothers and their children, very difficult.

During the recruitment process study subjects have disclosed concern or discomfort related to large vehicles coming to their homestead. The homesteads are located in a rural area, and there is minimal access to paved roads. While large vehicles better accommodate the rural terrain and needed numbers of field staff, the use of these vehicles in the area is atypical, and neighbors and other members of the community question their presence on a daily basis. In addition, some of the vehicles have a USAID logo. Within this population, USAID is often associated with HIV. The use of these large vehicles with the USAID logo discourages and prevents some individuals from enrolling in the study. Enrollment of other subjects in HNP was deterred by the frequency of visits by research staff, which has been reported as a barrier to recruitment. Some subjects were uncomfortable with unfamiliar research staff coming to their home on a regular basis.

Some of the individuals recruited for the study who chose not to participate disclosed a general distrust of the research itself. They perceived that the HNP biscuits, used as a daily dietary supplement in the food-based intervention "have a hidden agenda." Recruitment workers report that some women stated they believed the biscuits were related to infertility for both themselves and their children.

Retention barriers related to stigma. The HNP team is in the process of collecting qualitative data related to retention barriers associated with stigma. To date, nine mothers have withdrawn from the study. We have also been informed about isolated reports of domestic violence within our study population. The nature of HNP study participation affects not just the recruited mothers and their children, but all members of the household, as participation is an often highly visible activity to the community, and relatively time intensive. For example, it was found that after enrolling in the study, some of the married women discovered an opposition to participation by their husbands. Some fathers also did not allow their children to participate in the study. Two women decided following enrollment and participation that the frequent visits were more than they could handle, and chose to withdraw, reporting that the frequent visits became questionable to friends and neighbors and the community at large.

Figure 1. Directly observed treatment (DOT) workers deliver the nutrition intervention biscuits daily to HIV-infected women and their children in rural Kenya using motorbikes. The use of motorbikes allows research staff to more effectively "blend-in" with the respective study communities, and provokes less attention from neighbors allowing a greater measure of privacy for study enrollees. Photo by Elizabeth Buluku.

Practical Implications

While we acknowledge the difficulty in engaging the HIV-infected and affected in research, especially applied research like the HNP food-based nutrition intervention study, it is critical for the research and development communities to continue targeting this vulnerable group for improvements in quality of life and livelihood enhancement. However, continued engagement requires that barriers related to the stigmatization of HIV/AIDS be addressed and integrated into program planning. To address these barriers, HNP has employed the following strategies:

- Utilize outreach staff from the USAID-AMPATH clinic in Turbo to assist with the recruitment process. AMPATH outreach workers are embedded in the communities and have pre-existing relationships with the clients. They have developed rapport limiting the anxiety, fear, and mistrust associated with new activities.

- Recruit mothers from the USAID-AMPATH clinic site when they come for their clinic visits. Utilizing an established locally trusted center like the AMPATH clinic extends a measure of community support, trust, and acceptance to new programs, along with an accountability and legitimacy, and minimizes outreach efforts required for program acceptance among the study community.

- Use a cohort of active participants to discuss the project with potential subjects during recruitment. This creates a "peer to peer" diffusion of experience and knowledge alleviating mistrust and anxiety, and greatly enhances the probability of enrollment.

- Train research staff to be empathetic to stigma, and request that workers develop relationships with subjects. For an intensive intervention-based project like HNP, relationships between staff/team members and participants is critical to success, not only from a research standpoint, but from a moral and ethical one as well.

- Utilize motorbikes (Figure 1) to conduct daily home visits. The use of motorbikes allows research staff to more effectively "blend-in" with the respective study communities, and provokes less attention from neighbors allowing a greater measure of privacy for study enrollees.

- Park larger project vehicles, or vehicles that display the USAID logo some distance from the home and walk to the homesteads. Like the use of the motorbikes (Figure 1), this practice diminishes the association of household visits with HIV/AIDS, and offers more privacy to study participants.

- Encourage spouses to attend the study/project introduction sessions, and require that women with spouses share the study and the consent form with their spouses before consenting. When recruiting at the household level, especially when targeting women and children, it is critical to engage male household members. Males are often the heads of the household, and their level of support for family participation can mean the difference between a successful intervention, or harm to participants.

- Develop staff public relation skills. Having a staff with the capacity to promote the study/project can provide significant benefits to the acceptance and support of the study/project, especially at the community level, where staff often act as the "face" of a project.

- Use plain language to clearly identify the risks and benefits of participation. Transparency is key to ensuring that all potential enrollees are informed of costs and benefits to participation. In addition, continued discussion of these risks throughout the study provides encouragement and appreciation for the hardships a study/project may present.

- When appropriate, refer subjects to the counseling department at the AMPATH clinic. The provision of psychological and social support networks can drastically improve a participant's situation, as it helps to alleviate the sense of isolation and hardship that stigma may provide.

Lessons Learned

It is evident from the experience of HNP that future studies targeting the HIV-infected and affected must consider the impact of stigma carefully. It is recommended that similar studies conduct focus groups with the study population prior to piloting, to ensure stakeholder input and an understanding of the particular challenges and concerns within a local context. We have found that an existing relationship between the study staff and study subjects enhances positive outcomes related to recruitment and enrollment. Future studies should employ individuals known in the community that the population trusts to assist with recruitment. Finally, factors that identify study staff, or associate subjects with the study should be minimal to reduce the risk of disclosing a subject's HIV status.

Further Reading

Lieber, E., L. Li, Z. Wu, M.J. Rotheram-Borus, J. Guan, and the National Institute of Mental Health (NIMH) Collaborative HIV Prevention Trial Group. 2006. "HIV/STD stigmatization fears as health-seeking barriers in China." *AIDS and Behavior,* 10(5): 463-471.

Nyandiko, W., A. Siika, J. Ernst, G. Ettyang, C. Neumann, and C. Yiannoutsos. 2008. "The Academic Model Providing Access to Healthcare (AMPATH) in Kenya." *Research Brief 08-03-HNP.* Global Livestock Collaborative Research Support Program (GL-CRSP), University of California – Davis, Davis, CA.

Ortiz, O. 2008. *Stigma and Discrimination in HIV Counseling and Testing Services in the Private Health Sector in Guatemala: A Qualitative Study.* Bethesda, MD: Private Sector Partnerships - One project, Abt Associates Inc.

Smit, J., L.G. Bekker, K. Middelkoop, L. Myer, G. Lindegger, L. Schwartz, S. Seedat, T. Tucker, R. Wood, L. Bekker, and D.J. Stein. 2005. "Socio-behaviour challenges to phase III HIV vaccine trials in sub-Saharan Africa." *African Health Sciences* 5(3).

Srivastava, A. "Against all odds." *India Today*, June 18, 2009. Available online: http://indiatoday.intoday.in/site/Story/47426/Offtrack/Against+all+odds.html?page=0.

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The GL-CRSP HIV Nutrition Project (HNP) is evaluating the effect of protein quality and micronutrients in meat on the health and nutritional well-being of women living with HIV in rural Kenya and the health and development of their children by means of randomized controlled feeding intervention study. The project is led by Dr. Judith Ernst, Indiana University. Email: jernst@iupui.edu, and by Dr. Grace Ettyang, Moi University, Kenya. Email: gaettyang@gmail.com.

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